Cairo University

KASR ALAINY
CAIRO UNIVERSITY - FACULTY OF MEDICINE

Faculty of Medicine, Cairo University Postgraduate Research Protocol Template

1. **Study**

a- Proposed Study Title: ***Myopia Progression Control Using Atropine 0.05% After Pediatric Cataract Surgery And Intraocular Lens Implantation Surgery: A Randomized Clinical Trial.***

b- Degree: MD Degree

c- Date of Registration of MD: 10/2025

2. Candidate

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4. Scientific committee approval

Date of approval: 01/05/2026

5. Background and Rationale:

Cataract is a leading cause of visual impairment in the pediatric age group, with an annual incidence of 1.8 to 3.6 per 10,000[1]. The visual morbidity is not only due to media opacity caused by the cataracts, but also secondary to long lasting effects following cataract extraction, with timing and biometric aim of IOL implantation procedure presenting a unique challenge[2].

Normal ocular growth is characterized by axial length elongation along with corneal and lenticular flattening with a net refractive shift of approximately -0.9D[3,4]. Cataract surgery in infants interrupts normal emmetropization of eyes and can lead to large myopic shift which may reach over 10 D[5].

Myopia is an epidemic with an estimated increase in prevalence to 50% by 2025[6]. Rapidly progressing myopia significantly increases risk of permanent visual loss due to several ocular complications as maculopathy, retinal detachment and glaucoma[7].

Strategies for myopia control and prevention involve both optical and pharmacological measures, with atropine being a cornerstone in myopia management[8]. Initially, it was believed that atropine limits myopia progression via blocking accommodation. Recently, however, it has been shown that atropine functions via a non-accommodative pathway[9]. It is hypothesized that atropine exerts its action via regulation of dopamine release in retinal amacrine cells, which leads to reduction of rate of axial growth of eye[10]. Another plausible mechanism is that up- and down-regulation of scleral muscarinic receptors influences scleral matrix deposition[11]. Multiple low-dose concentrations have been studied, with older age and lower grades of myopia showing better response. Younger age requires the highest available concentration (0.05) to achieve adequate response[12].

While research exploring peripheral myopic defocus for post-cataract surgery myopia prevention shows promising results[13], the use of multifocal intra-ocular lenses (IOLs) cannot be used liberally in countries with high disease burden and challenged economies due to high price and decreased availability. To date there are no studies evaluating the use of topical atropine for the management of myopic shift following pediatric cataract surgery.

We aim to explore the use of 0.05% topical atropine in the prevention and management of myopic shift following pediatric cataract surgery.

6. Objectives:

-Primary objective:
To evaluate the effect of atropine eye drops 0.05% on myopia progression in unilateral and bilateral cases of pseudophakia.

-Secondary objective:
To evaluate side effects of atropine use as mydriasis leading to photophobia, blurring, and local allergic responses, rebound of myopia after cessation of atropine.

7. Study Design:
Randomized clinical trial

Study Methods

Population of study: The study will be performed on pediatric patient who underwent primary or secondary intraocular lens (IOL) implantation.

Study location: The study will be carried out in the Cairo University Pediatric Ophthalmology and Strabismology unit, Abu El Rish.

Inclusion criteria:

1) Children after IOL implantation (primary or secondary)
2) Age 1-7 years

Exclusion criteria:

1) Eyes with post-operative media opacity hindering adequate assessment of refraction
2) Eyes with complicated surgeries (e.g. vitreous loss, dropped lens matter requiring PPV, retinal detachment, etc)
3) Retinal pathologies
4) Glaucoma (congenital or secondary to surgery)
5) Anterior or posterior segment anomalies

Methodology in detail:
All guardians of the selected patients will receive a thorough explanation of the study design and aims and will sign an informed consent.

Baseline pre-treatment evaluation:

Ophthalmological:

- Cycloplegic refraction using both manual retinoscopy and autorefractometer – N.B. target refraction following surgery is adjusted to according to age (+4.00 at 1 year, +2-3 at 2-5 years and 0 above 5 years of age.)
- Corrected distance visual acuity (CDVA) whenever possible
- Slip lamp examination
- Intraocular pressure measurement using Perkin's applanation tonometry.
- Dilated fundus examination by binocular indirect ophthalmoscopy.
- Evaluation of extraocular motility and muscle balance.
- Stereopsis using Titmus test whenever possible
- Axial length measurement
    - Optical biometry (at least 5 measurements) in cooperative children
    - If child is uncooperative, A-scan ultrasonography via contact method, by 2 different observers
- Time spent outdoors and time of near work.

Randomization will be done by closed envelope technique and study participants will be divided into 2 groups: group A will receive the atropine eye drops 0.05% once per day and group B will receive placebo eye drops. Patients with bilateral surgery will receive atropine 0.05% in both eyes or placebo eyedrops in both eyes. Patients with unilateral pseudophakia will be randomized either atropine or placebo eyedrops.

Atropine 0.05% ED will be prepared by one specialized pharmacy (BKC Company, registration number Toll/332) and provided by Cairo University Pediatric Ophthalmology and Strabismology unit, Abu El Rish with monthly refills.

The study will be double masked as the investigators and patients will be blinded as regards the 2 groups. (to ensure no bias in the assessment by the investigators).
The study period is to be 12 months.

Follow up will be done at 6 weeks, 3, 6 ,9, 12 months: at each follow up the following will be assessed:

- Cycloplegic refraction manual retinoscopy and autorefractometer
- Corrected distance visual acuity (CDVA) whenever possible
- Stereopsis using Titmus test whenever possible
- Ocular muscle balance.
- Axial length measurement
    - Optical biometry (at least 5 measurements) in cooperative children
    - If child is uncooperative, A-scan ultrasonography via contact method, by 2 different observers

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- Time spent outdoors and time of near work.
- Compliance (measured in days atropine used per week)

The research involves:
Human participants

Type of consent of study participants:
Written consent

Potential risks:
Risks of treatment: Mydriasis leading to photophobia, and local allergic responses, rebound of myopia after cessation of atropine.

Confidentiality of data:
All participants will be coded, and data entry will occur using these codes. All data of the patients will be saved in secure files.

9- Study outcomes:

Primary outcomes:

1- Change in spherical equivalent measured in diopters in each group.
2- Change in axial length measured in millimeters in each group.

Secondary outcome parameters (other outcomes to be assessed)

1- Side effects of atropine use as mydriasis leading to photophobia, blurring, and local allergic responses, rebound of myopia after cessation of atropine.

10- Sample size:

Sample size was calculated based on a recent study comparing axial length changes following pediatric IOL implantation using monofocal and multifocal IOLs[13] as no studies comparing atropine use following pediatric cataract surgery exists. The effect size was estimated 0.78 and accordingly a **total of 44 eyes** were calculated using G*power (3.1.9.4) software, the power being 0.8. The Type I error probability associated with this test of the null hypothesis is 0.05. With dropout rate 10%, sample size will be **50 eyes, 25 in each group.**

11- Statistical analysis

The collected data will be statistically analyzed using SPSS program (Statistical Package for Social Science) version 26.

A. Descriptive statistics:

Quantitative data will be expressed as mean and SD while qualitative data will be represented in tables as frequencies and percentages.

B. Analytical statistics:

1) Student t test will be used for comparing quantitative data. It is considered statistically significant at P-value < 0.05.

2) Chi-square test will be used for qualitative data. It is considered statistically significant at P-value < 0.05

12- Source of funding: Cairo University Ophthalmology
Faculty of Medicine, Cairo University

14- References:

1. Sheeladevi S, Lawrenson JG, Fielder AR, Suttle CM. Global prevalence of childhood cataract: a systematic review. *Eye Lond Engl*. 2016;30(9):1160-1169. doi:10.1038/eye.2016.156

2. Magli A, Forte R, Rombetto L. Long-term outcome of primary versus secondary intraocular lens implantation after simultaneous removal of bilateral congenital cataract. *Graefes Arch Clin Exp Ophthalmol*. 2013;251(1):309-314. doi:10.1007/s00417-012-1979-7

3. Gordon RA, Donzis PB. Refractive development of the human eye. *Arch Ophthalmol Chic Ill 1960*. 1985;103(6):785-789. doi:10.1001/archopht.1985.01050060045020

4. Valeina S, Heede S, Erts R, et al. Factors influencing myopic shift in children after intraocular lens implantation. *Eur J Ophthalmol*. 2020;30(5):933-940. doi:10.1177/1120672119845228

5. McClatchey SK, Parks MM. Myopic Shift After Cataract Removal in Childhood. *J Pediatr Ophthalmol Strabismus*. 1997;34(2):88-95. doi:10.3928/0191-3913-19970301-07

6. Medina A. The cause of myopia development and progression: Theory, evidence, and treatment. *Surv Ophthalmol*. 2022;67(2):488-509. doi:10.1016/j.survophthal.2021.06.005

7. Bullimore MA, Ritchey ER, Shah S, Leveziel N, Bourne RRA, Flitcroft DI. The Risks and Benefits of Myopia Control. *Ophthalmology*. 2021;128(11):1561-1579. doi:10.1016/j.ophtha.2021.04.032

8. Chen JW, Lu CJ, Yu CH, Liu TC, Wu TE. Decision Tree Modeling to Predict Myopia Progression in Children Treated with Atropine: Toward Precision Ophthalmology. *Diagnostics*. 2025;15(16):2096. doi:10.3390/diagnostics15162096

9. Kaiti R, Shyangbo R, Sharma IP. Role of Atropine in the control of Myopia Progression- A Review. *Beyoglu Eye J*. 2022;7(3):157-166. doi:10.14744/bej.2022.07742

10. Read SA, Alonso-Caneiro D, Vincent SJ, Collins MJ. Longitudinal changes in choroidal thickness and eye growth in childhood. *Invest Ophthalmol Vis Sci*. 2015;56(5):3103-3112. doi:10.1167/iovs.15-16446

11. Barathi VA, Beuerman RW. Molecular mechanisms of muscarinic receptors in mouse scleral fibroblasts: Prior to and after induction of experimental myopia with atropine treatment. *Mol Vis*. 2011;17:680-692.

12. Li FF, Zhang Y, Zhang X, et al. Age Effect on Treatment Responses to 0.05%, 0.025%, and 0.01% Atropine: Low-Concentration Atropine for Myopia Progression Study. *Ophthalmology*. 2021;128(8):1180-1187. doi:10.1016/j.ophtha.2020.12.036

13. Du Q, Zhang Y, Huang Y. Peripheral Refraction and Axial Growth Rate After Multifocal or Monofocal Intraocular Lens Implantation in Chinese Pediatric Cataract Patients. *Invest Ophthalmol Vis Sci*. 2025;66(2):33. doi:10.1167/iovs.66.2.33

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